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10/668,629	09/23/2003	James P. Delaney	10123/03501	2181

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EXAMINER	
JOHNSON, JERROLD D	

ART UNIT	PAPER NUMBER
3728	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/668,629	DELANEY ET AL.	
	Examiner	Art Unit	
	Jerrold Johnson	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 1-9,12, 13, and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullman US 6,569,106.

Re claim 1, Ullman discloses in Fig. 4 a protective package for an elongated medical device, comprising:

a protective sheath 27 including a lumen sized to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device, and

a hydration opening disposed between the first and second ends of the sheath.

Re claim 2, the sheath is formed as a hoop and wherein the medical device is a catheter. Note Col. 3 lines 29 and 30. Additionally, small ended catheters, such as are shown by Talonn US 3,606,001, which herein serves as extrinsic evidence, are representative of a type of catheter which would require little, if any modification to the protective package of Ullman to accommodate.

Re claim 3, a protective assembly 18 is disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end.

Re claim 4, a luer 30 is attached to the sheath in fluid contact with the lumen, the luer defining the hydration opening.

Re claim 5, an adapter 30 is coupled to the hydration opening capable of receiving a syringe.

Re claim 6, the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device, through the size of the funnel shaped opening 18, which would accommodate the distal end.

Re claim 7, the sheath is adapted to contain one of a catheter, a guide wire and a medical coil.

Re claim 8, the sheath is adapted to contain a catheter with a shaped distal tip. Again, reference is made to the funnel opening, which may or may not be needed to accommodate a shaped distal tip, as the shaped distal tip of some catheters is of a size that approximates the size of the remainder of the catheter, as is shown in Talonn.

Re claim 9, the hydration opening is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 12, the hydration opening appears to be oriented to direct an amount of flow toward the first end which is different than an amount of flow directed toward the second end.

Re claim 13, the hydration opening is positioned so that, the difference in the amounts of flow toward the first and second ends achieves a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 15, Ullman discloses a catheter kit comprising

a catheter having a shaped distal tip;

a tubular enclosure 27 having a length and an inner diameter corresponding, respectively, to a length and outer diameter of the catheter;

a first end of the tubular enclosure 18,21 being adapted to receive the shaped distal tip;

a second end of the tubular enclosure being adapted to receive a proximal end of the catheter, and

a hydration opening 30 extending into an interior of the tubular enclosure between the first and second ends thereof, the hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends.

Re claim 16, a protective structure 18,21 is disposed at the first end, the protective structure maintaining a desired curvature of the shaped distal tip.

Re claim 17, the tubular enclosure is coiled to form a hoop.

With respect to Applicant's arguments, firstly, the arguments address alleged deficiencies of the disclosure of Ullman in Fig. 1, when the rejection clearly sets forth the specific embodiment of Fig. 4. Additionally, Applicant has also ignored the recitation of Col. 3, lines 29 and 30, which were set forth in the rejection, and which address the applicability of the invention to accommodate catheters.

Applicant's argument that the device of Ullman is not a sheath is noted, but also found to be non-persuasive. Merriam-Webster's Collegiate Dictionary, tenth edition, sets forth the following definition of sheath: any of various covering or supporting

structures that are applied like or resemble in appearance *or function* (italics added) the sheath of a blade. Clearly Ullman discloses a structure which meets the definition, particularly with respect to the function of a sheath of a blade.

Applicant's arguments drawn to Ullman not being adapted to receive the shaped distal tip are noted, but this argument was addressed in the previous rejection a portion of which is provided again below:

"Re claim 1, Ullman discloses in Fig. 4 a protective package for an elongated medical device, comprising:

a protective sheath 27 including a lumen sized to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device, and

a hydration opening disposed between the first and second ends of the sheath.

Re claim 2, the sheath is formed as a hoop and wherein the medical device is a catheter. Note Col. 3 lines 29 and 30. Additionally, small ended catheters, such as are shown by Talonn US 3,606,001, which herein serves as extrinsic evidence, are representative of a type of catheter which would require little, if any modification to the protective package of Ullman to accommodate."

Applicant's arguments directed to the "tip 16a is never received by the chamber 13" are noted, but not persuasive. The claim recites a first end adapted to receive a distal end... and a second end adapted to receive a proximal end. The rejection addresses these broad recitations. The recitation "adapted to receive" does not set

forth a specific arrangement that is not disclosed by Ullman. The adapted to receive recitation does not set forth with any specificity exactly how the ends are received. And, although Ullman in his disclosure of accommodating a guidewire suggest leaving a portion of the guidewire extended from the sheath, that in no way suggests that the sheath is not *suitable* to accommodate the guidewire. Clearly the lumen of Ullman *is suitable* to receive the entire guidewire, if desired. For example, were the end of the guidewire disposed entirely within the conical funnel, it would thus be *received* in the funnel, and accordingly, would meet the claim language. Additionally, were Ullman accommodating catheters, as he suggests, the same situation would be present. In the funnel portion is configured such that in both of these situations (guidewire or catheter) the funnel portion is suitable to receive the end of the guidewire or catheter entirely within the funnel portion, and yet still allow easy removal of the guidewire or catheter from the package.

Finally, with respect to Ullman not disclosing a "hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends." Clearly, from Fig. 4, fluid entering into the port 30 will go "toward the first and second ends", as both ends are below the port 30. However, even if the first end 26 were higher that port 30, which it is not, and no fluid went toward the first end, the claim limitation would still be met. Claims 9 and 15 recite: a "hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends", if the proportion is all the fluid directed to one end and none of the fluid directed to the other end, the claim limitation is met.

2. Claims 1-7 and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Samuels US 6,588,588.

Re claim 1, Samuels discloses in a protective package for an elongated medical device, comprising:

a protective sheath including a lumen sized to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device, and

a hydration opening 10 disposed between the first 42 and second 46 ends of the sheath.

Re claim 3, a protective assembly the inside of the lour 10 is disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end.

Re claim 4, a luer 10 is attached to the sheath in fluid contact with the lumen, the luer defining the hydration opening.

Re claim 5, an adapter 10 is coupled to the hydration opening capable of receiving a syringe.

Re claim 6, the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device.

Re claim 7, the sheath is adapted to contain one of a catheter, a guide wire and a medical coil.

Re claim 9, the hydration opening 10 is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 10, the desired ratio is one to one. The one to one ratio is achieved as the flow of fluid into the first end will necessarily flow through the second end, as the ends are connected.

Re claim 11, the hydration opening is substantially equidistant from the first and second ends.

Re claim 12, the hydration opening is oriented to direct a greater amount of flow toward the first end which is than an amount of flow directed toward the second end. The flow is initially directed toward the first end 42, but thereafter the desired ratio of fluid flow at the first end and second end will be equalized as the fluids flow through the sheath toward the other ends, achieving one to one flow upon the filling of the sheath.

Re claim 13, the hydration opening is positioned so that, the difference in the amounts of flow toward the first and second ends achieves a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 14, the desired ratio is one to one.

Applicant's arguments with respect to Samuels are noted but are also not persuasive. Samuels does in fact disclose an opening 30 suitable to perform the

intended use as a hydration opening. Samuels in US 6,375,006 clearly provides the extrinsic evidence that one of ordinary skill art would find the hydration opening of Samuels 30 suitable for the intended use as a hydration opening.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 8, and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samuels US 6,588,588 in view of Ullman.

Samuels, as stated above, discloses the claimed features of claims 1-7 and 9-14, but does not disclose his package being used with a catheter.

Samuels further discloses the structure of the package as claimed with the sheath being formed as a hoop but does not disclose the medical device is a catheter.

Again, Ullman discloses in col. 3 lines 29 and 30 the use of a guidewire package being used to protect and hydrate catheters.

It would have been obvious to one of ordinary skill in the art to modify the package of Samuels, as Ullman suggests, to accommodate catheters. Additionally, small ended catheters, such as are shown by Talonn US 3,606,001, which herein

serves as extrinsic evidence, are representative of a type of catheter which would require little, if any modification to the protective package of Samuels to accommodate a catheter. There are inherent benefits brought on when the uses of an item, such as is disclosed by Samuels, are increased, as would be the case upon the slight modification of the package of Samuels suggested by Ullman.

Additionally, the sheath of Samuels would easily be adapted to contain a catheter with a shaped distal tip upon the modifications as taught by Ullman. Again, reference is made to the catheter of Talonn. Modifications may or may not be needed to accommodate a shaped distal tip in many catheters, like that disclosed by Talonn. This is because the shaped distal tip of some catheters, such as is disclosed by Talonn, are of a size that approximates the size of the remainder of the catheter.

Additionally, upon the filling of the sheath of Samuels with fluid, the proximal and distal ends are substantially equally hydrated. And, as was previously stated, the hydration opening is equidistant between the first and second ends.

With respect to Applicant's arguments addressing this rejection please note the response above.

4. Claims 1,3,6-9,12,13,15,16 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Taniguchi US 3,861,395.

Re claim 1,15 and 19, Taniguchi discloses (best seen in Figs. 1 and 3) a protective package for an elongated medical device (the micro-catheter), comprising:

a protective sheath including a lumen sized to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device, and

a hydration opening (beneath the reservoir 31, as seen in Fig. 3) disposed between the first end not identified and second 22 ends of the sheath. The proximal end 66 of the catheter is shown being extended past the second end 22 during use in Fig. 1, and recessed behind the second end 22 in Fig. 3).

Re claim 3, a protective assembly (not identified) is disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end.

Re claim 6 and 16, the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device.

Re claim 7, the sheath is adapted to contain one of a catheter, a guide wire and a medical coil.

Re claim 9, the hydration opening is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 12, the hydration opening is oriented to direct a greater amount of flow toward the first end which is than an amount of flow directed toward the second end.

Re claim 13, the hydration opening is positioned so that, the difference in the amounts of flow toward the first and second ends achieves a desired ratio of fluid flow at the first end to fluid flow at the second end.

With respect to Applicant's arguments, the Examiner set forth in the rejection the interpretation of Taniguchi as having:

a hydration opening (beneath the reservoir 31, as seen in Fig. 3) disposed between the first end not identified and second 22 ends of the sheath. The proximal end 66 of the catheter is shown being extended past the second end 22 during use in Fig. 1, and recessed behind the second end 22 in Fig. 3).

Applicant's arguments do not address this interpretation and are not understood by the Examiner. Clearly in Fig. 3, the hydration opening (beneath the reservoir 31, as seen in Fig. 3) is disposed between the first end of the sheath (the closed end of the bag, which is not identified) and the second end 22 of the sheath.

5. Claims 4 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Taniguchi US 3,861,395 in view of Hodgkins US 4,805,611.

Taniguchi discloses the claimed features but does not disclose a luer or adapter capable of receiving a syringe.

Hodgkins discloses a luer or adapter 67 capable of receiving a syringe.

It would have been obvious to one of ordinary skill in the art to modify the sheath of Taniguchi with the much simpler construction of an irrigation port as taught by Hodgkins so as to allow the use of syringes to administer a desired amount and type of irrigation compound or lubricant.

No arguments were presented with respect to this rejection.

6. Claims 1,4,7,9,10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Laak US 5,597,264.

Re claim 1, Laak discloses on the first page of the patent a protective package capable of accommodating an elongated medical device, comprising:

a protective sheath disposed between end caps 14b including a lumen of a size that is capable to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device, and

a hydration opening 12 disposed between the first and second ends of the sheath.

Re claim 4, a luer 12 is attached to the sheath in fluid contact with the lumen, the luer defining the hydration opening.

Re claim 7, the sheath is easily of a size such that it is adapted to contain one of a catheter, a guide wire and a medical coil.

Re claim 9, the hydration opening is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 10, the desired ratio is one to one. The one to one ratio is achieved as the flow of fluid into the first end will necessarily flow through the second end, as the ends are connected.

Re claim 11, the hydration opening is substantially equidistant from the first and second ends.

Note that the claims 1,4,7,9,10 and 11 are of such breadth so as to read on a variety of structures like Laak, which both disclose the structure defined therein, as well as meeting the standard of being capable of providing the intended use described therein.

With respect to Applicant's arguments of the rejection over Laak, it is noted that the claims do not set forth an elongate medical device, but instead broadly set forth the intended use of the package with an elongate medical device. Accordingly, the MPEP in 2111.02 sets forth the Patent Office policy with respect to handling intended use limitations consistent with In re Schreiber. If a prior art structure is capable of performing the intended use as recited in the preamble then it meets the claim. The test is not whether one "would" use the package of Laak with an elongated medical device, but whether or not one "could". Laak is capable of performing the intended use.

Conclusion

None of the Applicant's arguments are persuasive and all previous rejections are maintained. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerrold Johnson whose telephone number is 571-272-7141. The examiner can normally be reached on 9:30 to 6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Mickey Yu
Supervisory Patent Examiner
Group 3700